EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 752691 R000

Manufacturer: American Orthodontics Corporation

Address:
3524 Washington Avenue
Sheboygan
Wisconsin
53081
USA

Single Registration Number: US-MF-000007702

EU Authorised Representative: Medical Technology Promedt Consulting GmbH

Address:
Ernst-Heckel-Straße 7
66386 St. Ingbert
Germany

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2023-01-19**

Current Issue Date: **2023-06-02**

Starting Validity Date: **2023-06-02**

Expiry Date: **2028-01-18**

...making excellence a habit.™

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 752691 R000

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Orthodontic Devices	Class IIa

First Issue Date: **2023-01-19**

Current Issue Date: **2023-06-02**

Starting Validity Date: **2023-06-02**

Expiry Date: **2028-01-18**

...making excellence a habit.™

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 752691 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2023-01-19	3480898	Issued.
Current	3856070	Supplemented: Change to the device group name on the certificate from Orthodontic Brackets, Bondable Devices & Tubes to Orthodontic Devices

First Issue Date: **2023-01-19**

Current Issue Date: **2023-06-02**

Starting Validity Date: **2023-06-02**

Expiry Date: **2028-01-18**

...making excellence a habit.™

Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A Member of the BSI Group of Companies.